

**REMARKS**

The present Amendment is in response to the Official Action mailed July 21, 2008. Because of the finality of the Action, the present Amendment is being submitted with a Request for Continued Examination. Claims 1, 4, 5, 8-10, 13, 14, 17, and 18 have been amended, claims 11 and 19-24 have been previously canceled, and claim 25 is new. Thus, claims 1-10, 12-18 and 25 remain pending in the present case. The following sets forth Applicants' remarks pertaining to the currently pending claims and the outstanding Action.

As an initial matter, Applicants respectfully thank the Examiner for conducting the telephone interview of December 23, 2008, with regard to the present case and two other related cases that the Examiner is handling. Specifically, in that telephone discussion, which is evidenced by the Examiner's Interview Summary dated January 13, 2009, the present case and U.S. Patent Application Nos. 10/781,506 and 10/781,507 were discussed. In addition, it was brought to the Examiner's attention that at least one other case in the family of cases relating to the present case includes similarly claimed subject matter (i.e., U.S. Patent Application Serial No. 10/781,504). Telephone discussions with the Examiner (i.e., Examiner Schillinger) handling that latter case were conducted on January 14 and 16, 2009. In an Information Disclosure Statement accompanying the present case, those cases, as well as prior art cited in connection with them, have been listed. Should the Examiner wish to review any prosecution documents pertaining to any of these cases, Applicants would be glad to provide copies of same. In the aforementioned telephone discussion, the Examiner indicated, at least initially, that such would not be necessary.

Further in the December 23<sup>rd</sup> telephone discussion, the outstanding Action was discussed in detail. Specifically, Applicants' undersigned counsel provided arguments as to why the insertion plate arrangement of the present invention was very different from that of the cited prior art. Namely, Applicants' undersigned counsel explained to the Examiner that the element referred to by the Examiner as meeting the insertion plate limitation of the previously presented case in U.S. Patent No. 5,246,458 to Graham ("*Graham*") simply operates in a different fashion than the insertion plate of the present invention. In particular, the element referred to by the Examiner in *Graham* as being an insertion plate (i.e., element 42) is not directly connected with the first and second members of the vertebral disc replacement device of that reference. Rather, arcuate plate (42) of *Graham* is only attached to one of those members at any given time.

On the other hand, the present invention teaches its insertion plate 700 as being coupled with mounting screw holes 509, 609 of the intervertebral disc replacement device 400 of the present invention, thereby leaving bone screw holes 508a, 508b, 608a, 608b capable of receiving bone screws while the insertion plate is still coupled to the device. Moreover, insertion plate 700 is detachably coupled with an insertion handle 800, so as to allow for the construct made up of device 400 and insertion plate 700 to be manipulated by the handle when coupled and to stand alone when uncoupled. As is more specifically set forth in paragraph [0069] of the originally-filed specification of the present case, this provides the benefit of placing the two components of the intervertebral disc replacement device in a familiar fashion to the surgeon, i.e., similar to that of a spinal plate (an example of which is shown in Figs. 13a-13d). The Examiner agreed that

this was indeed a significant difference between the present invention and that of *Graham*, and indicated that claim amendments that more specifically capture these differences would likely overcome the rejections set forth in the Action. In particular the Examiner suggested that independent claims 1 and 10 be amended to require that the first and second members be separable from one another and that the insertion plate be directly connected with both the first and second members. As will be discussed more fully below, Applicants have made these amendments.

Turning now to the substance of the Action, the Examiner set forth the following rejections of the previously presented claims:

- Claims 1-4, 6, 7, 10, 12, 13, 15, and 16, under 35 U.S.C. § 102(b) as being anticipated by *Graham*.

- Claims 8, 9, 17, and 18, under 35 U.S.C. § 103(a) as being obvious over *Graham*.

Essentially, the Examiner asserted that *Graham* teaches each and every one of the limitations of claims 1-4, 6, 7, 10, 12, 13, 15, and 16, and that claims 8, 9, 17, and 18 would have been obvious to one of ordinary skill in the art at the time of the present invention in light of *Graham*. Independent claims 1 and 10 have been amended above to require that the first and second members be separable from one another, and that the insertion plate be removably and directly connected with both the first and second members. Moreover, such claims have also been amended to more specifically capture the structure of the intervertebral disc replacement device, in that they now require that each of the first and second members include at least one bone screw hole and at least one mounting screw hole. This particular configuration, as is alluded to above, allows for the two-piece intervertebral disc replacement device to be presented

by way of the insertion plate in a manner similar to the use of a spinal plate. Finally, such claims have been amended to require that the insertion plate have a perimeter, and that the perimeter not extend over the first and second bone screw holes when the insertion plate is connected with the first and second mounting screw holes. While Applicants do not agree that the limitations of the previously presented claims are taught by *Graham* (in particular, Applicants do not believe the drill guide limitations to be met), they note that it is clear that these additional limitations are not taught by *Graham*. Thus, Applicants respectfully submit that independent claims 1 and 10 are neither anticipated nor obviated by *Graham*.

Further in the Action, the Examiner also noted claims 5 and 14 as being objected to as being dependent upon a rejected base claim, but allowable if rewritten in an independent form, including all of the limitations of the base claim and any intervening claims. Applicants respectfully thank the Examiner for this indication, and note that they have presented new independent claim 25 which incorporates the subject matter of previously presented independent claim 1 and dependent claims 3-5 (*i.e.*, the subject matter noted as allowable by the Examiner). Given the Examiner's indications in the Action, Applicants respectfully submit that this new independent claim is also neither anticipated nor obviated by any of the prior art of record.

Finally, although not specifically discussed above, each of the remaining claims, certain of which have been amended for consistency purposes, are also neither anticipated nor obviated by any of the prior art based upon their proper dependence from one of independent claims 1 or 10, or an intervening claim. Any of these allowable dependent claims may, in fact, also include subject matter even more clearly not taught by the prior art,


and Applicants reserve the right to argue such at a later date, if necessary. Therefore, in light of the above, Applicants respectfully request allowance of each and every one of the currently pending claims.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited. If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: January 21, 2009

Respectfully submitted,

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